

REMARKS

Claims 1-4, 6-15, 17-28 are pending in this application. Claims 4, 6, 7, 11, 13, 15, 17-19, 22 and 25-27 have been withdrawn without prejudice to their subject matter. Claims 1-3, 8-10, 12, 14, 20, 21 and 23 stand rejected. Claim 28 is new.

ELECTION / RESTRICTION

As of the filing of this paper no decision has been made on the petition to withdraw the election of species made on August 31, 2004. Consequently, several claims remain withdrawn from examination, however, this status is subject to change pending the outcome of the petition.

INFORMATION DISCLOSURE STATEMENT.

This issue is resolved as the Office action indicates that the two references identified on the 1449 filed on 12/02/03 (U.S. patent 6,146,358 and EPO 0 835 673) have been considered.

Drawing Rejections/Objections

The proposed amendments to figures 5 and 16 stand rejected as allegedly introducing new matter into the drawings predicated upon 37 C.F.R. 1.121(f). However, the proposed amendments to both figures do not introduce new matter as there is more than adequate enabling support for them in the as-filed application.

As to figure 5, and as explained in earlier correspondence, the specification provides support for this figure at paragraph 25 of the published application. Nevertheless, without citation to any reference, the Office action contends that there is no support for the figure as characterized in amended figure 5. In response a Declaration from Dr. Palasis is being filed in support of the drawing amendment to claim 5. In her Declaration, Dr. Palasis states that paragraph 25 would be interpreted by one of skill in the art to mean "that an inside surface of the balloon may contain multiple ribs, notches, or other configurations that increase the

deformability of the balloon.” She continues by stating that “[t]hese configurations can include notches and ribs that form grooves with parallel walls and square bases as shown in Amended Fig. 5 as well as other configurations, such as ‘V’ notches and ‘U’ notches.” Consequently, the undersigned submits that the amendment to figure 5 does not add new matter to the application as one of skill in the art would read the as-filed disclosure as including the material “as characterized in the amended figure 5.”

Figure 16 is rejected because it shows “the second balloon positioned between the dilation bladder and the first balloon and the grooves in the first balloon.” Support for the grooves is explained above. As to the second balloon, support can be found in as-filed claim 18 which provides “a second balloon positioned between the dilation bladder and the hyper-deformable inflatable balloon, the second balloon having an outside surface, the outside surface in communication with therapeutic.” Thus, one of skill would see this disclosure as being more than enough support for entry of figure 16. Still further, these figure amendments should be entered because they are not being filed for the purpose of supplementing the as-filed disclosure for the interpretation of any claim. For each of these reasons, the undersigned submits that the drawing amendment should be entered.

35 U.S.C. § 102

Claims 1, 2-3, 8-10, 20-21 and 23 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Crocker et al. (U.S. Pat. No. 5,295,962). The undersigned submits that Crocker does not disclose or suggest “the interior surface of the first inflatable balloon free from contact with the therapeutic when the exterior surface of the first inflatable balloon is at least partially covered with the therapeutic when the first inflatable balloon is in an initial unexpanded state,” as recited in claim 1. By comparison, in Crocker, therapeutic only reaches the outer

surface of the balloon only after the balloon has started to stretch and some of the therapeutic has squeezed through the balloon from within it. *See e.g.*, col. 2, lns. 47-55; col. 7, lns. 40-57.

Because the drug is expressed through the outer balloon in every embodiment of Crocker, it fails to teach or suggest a system having therapeutic on an interior surface as recited in claim 1.

As to the Office action's contention that "Crocker's device is capable of releasing the drug through the pores in an unexpanded state" the undersigned submits that this feature is not directly taught or even inherently present. In fact, the delivery of therapeutic through the outer balloon in Crocker doesn't begin until after the balloon is positioned and drug is delivered through an internal lumen of the device. This shortcoming of Crocker also renders claim 1 unpatentable over it.

As to claim 20, the undersigned also submits that Crocker does not disclose or suggest "inserting an expandable first membrane attached to a catheter into the vessel of the patient, the expandable first membrane having an exterior surface in contact with therapeutic." In Crocker, there is no disclosure or suggestion that the therapeutic will be in contact with the exterior surface of the balloon before or as the catheter is inserted into a patient. Instead, Crocker teaches that drug will be expelled from the balloons and come in contact with the exterior surfaces of the balloon only after the catheter is in position and drug has been fed into and through the drug delivery balloon 32. *See, e.g.*, Col. 7, lns. 2-57. For at least this reason, Crocker does not anticipate claims 20, 21 and 23.

35 U.S.C. § 103

Claims 1-3, 7-10, 12, 14, 20-21 and 23 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Pat. No. 6,471,672 by Brown et al ("Brown") or U.S. Pat. No. 5,704,913 by Abele et al ("Abele") in view of U.S. Pat. No. 5,304,121 by Sahatjian

("Sahatjian"). The undersigned submits that none of these references disclose or suggest "the elasticity of the first inflatable balloon being greater than the elasticity of the dilation bladder," as substantially recited in claims 1 and 20. As these references do not disclose or suggest this language, there is no need to address the impropriety of combining them.


CONCLUSION

Reconsideration and allowance of each of the pending claims is requested.

The Examiner is invited to contact the undersigned to discuss any matter concerning this application.

Respectfully submitted,

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